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Are RSV Vaccines for Babies Finally Here? CDC Panel Weighs Options for Next Season + More

The Defender's Big Pharma Watch delivers the latest headlines related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from other news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that affects human health and the environment.

By The Defender Staff

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Are RSV Vaccines for Babies Finally Here? CDC Panel Weighs Options for Next Season.

USA TODAY reported:

> On Thursday, the CDC's Advisory Committee on Immunization Practices will discuss two RSV vaccines by pharmaceutical giants GlaxoSmithKline and Pfizer, and a monoclonal antibody by Sanofi and AstraZeneca. Here's what we know.
>
> The Food and Drug Administration announced Wednesday it has agreed to review Pfizer's vaccine candidate, RSVpreF, for approval and set an action date for August 2023. If approved, the vaccine would be for pregnant people to help protect against RSV severe disease in infants from birth through 6 months.
>
> In the fall, the company announced results from a Phase 3 clinical trial showing its experimental vaccine protected infants when given to pregnant participants between 24 and 36 weeks of gestation. A Pfizer spokesperson said the company will present updated efficacy and safety data from its trial during Thursday's federal advisory meeting, including birth outcomes, as well as information broken down by race and ethnicity.
>
> The federal advisory panel will also discuss an RSV vaccine for adults 60 and older developed by GSK called AReSVi 006, which the FDA also accepted for priority review in November to approve. Federal advisers will also be discussing a monoclonal antibody, called nirsevimab, by Sanofi and

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AstraZeneca that helps prevent RSV lower respiratory tract disease in newborns and infants entering or during their first RSV season.

CDC Advisors Recommend Mpox Vaccine for at-Risk Adults in Future Outbreaks

CNBC reported:

> The Centers for Disease Control and Prevention's independent advisors on Wednesday unanimously recommended administering the two-dose Jynneos vaccine to adults at risk of mpox in the event of future outbreaks, following last year's unprecedented epidemic.
>
> The U.S. started using the Jynneos vaccine, made by the Danish company Bavarian Nordic, widely for the first time last summer after the Biden administration declared a public health emergency in response to the sudden spread of mpox domestically. The virus has historically been limited mostly to West and Central Africa but has now spread to more than 100 countries.
>
> The advisors' recommendation on Wednesday was not specific to men who have sex with men, the community most affected by the current epidemic. Although mpox is primarily spreading through sexual contact right now, Rao said it's unclear how the virus would transmit in a future outbreak and what communities might be most affected.
>
> The CDC advisors will meet again in June to discuss using the Jynneos vaccine for kids at risk of mpox in future outbreaks. The U.S. is currently offering the vaccine to adults and adolescents who are at risk in the current epidemic.

FDA Widens Advisory on Eye Products After Patients Blinded, Hospitalized

The Hill reported:

> The Food and Drug Administration (FDA) on Tuesday widened an advisory on artificial tear products to include additional ones manufactured by Global Pharma Healthcare Private Limited over concerns of potential bacterial contamination that could result in blindness or death.
>
> The FDA warning now urges consumers and healthcare professionals not to use EzriCare Artificial Tears, Delsam Pharma's Artificial Tears and Delsam Pharma's Artificial Eye Ointment, which are intended to be sterile.
>
> The manufacturer first recalled the artificial tears at the recommendation of the FDA due to what the agency says were violations of its current good manufacturing practice. Among the issues noted by the FDA were drug formulation issues, concerns about packaging and a lack of appropriate microbial testing.
>
> The Centers for Disease Control and Prevention (CDC) earlier this month warned against using the EzriCare or Delsam Pharma's Artificial Tears products as it investigated what it says is a potentially related string of some 56 Pseudomonas aeruginosa bacterial cases.

Moderna's Combination Skin Cancer Therapy Receives FDA's Breakthrough Tag

Reuters reported:

> Moderna Inc. (MRNA.O) said on Wednesday its experimental personalized mRNA skin cancer vaccine in combination with Merck & Co Inc.'s (MRK.N) drug Keytruda has received breakthrough therapy designation from U.S. regulators as an additional treatment for high-risk patients.
>
> The breakthrough tag is granted by the U.S. Food and Drug Administration (FDA) based on data from a mid-stage study of the drug that showed the therapy reduced the risk of skin cancer's recurrence or death by 44%

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compared with Keytruda alone.

The companies said they plan to initiate a late-stage study in the adjuvant treatment of melanoma in 2023.

$130,000 for Medicine Is Outrageous. Blame the Government, Not Pharmaceutical Companies.

USA TODAY reported:

One of my family members, who has multiple sclerosis, takes two prescriptions to treat the illness. Together, the medications cost $130,000 a year. Thankfully, her family's insurance and the MS LifeLines charity cover the majority of the cost. If not for the charity and her insurance, the medication would simply cost too much.

And one of those medications, Rebif, is over three times more expensive in the United States than in other countries. A lot of people, including President Joe Biden, blame "corporate greed" for such high prescription costs. But it's not that simple. In his State of the Union address this month, Biden said that expanding price controls to cover all Americans, and not just Medicare recipients, is the solution to lower pharmaceutical prices.

But more government intervention in the free market isn't the answer. In fact, one of the big reasons why drug prices are so high now is because the federal government protects the pharmaceutical industry from competition abroad.

Just as tariffs make U.S. products more expensive, the Food and Drug Administration makes prescriptions more expensive by prohibiting Americans from buying cheaper medication from other countries. But the biggest reason why drug prices are high is the 1984 Hatch-Waxman Act, which allows drugmakers to maintain a monopoly on new products until their patent expires.

Big Pharma's Looming Threat: A Patent Cliff of 'Tectonic Magnitude'

BioPharma Dive reported:

At the start of the last decade, big pharma was getting smaller. Blockbuster medicines that had fueled years of growth were losing patent protection, exposing the industry's largest companies to generic competitors. The resulting impact was so substantial it temporarily stalled the relentless upward march of U.S. drug spending.

Today, big drugmakers are facing an even larger "patent cliff," with more than $200 billion in annual revenue at risk through 2030. But this time around, many of the brand name drugs losing market exclusivity are biologic products, manufactured from living cells, rather than the chemical pills that previously dominated the ranks of pharma top-sellers.

These biologic drugs, like AbbVie's anti-inflammatory treatment Humira and Merck & Co.'s top-selling cancer medicine Keytruda, will face competition from so-called biosimilar drugs that, unlike generics, may not be as easily substitutable. Still, it will be a treacherous period for drugmakers to navigate, as they will need to replenish their research pipelines and carefully manage new product launches to replace lost revenue.

Moderna Inks Another Gene Editing Deal

BioPharma Dive reported:

Already well versed in using messenger RNA to create vaccines, Moderna, through its latest partnership, hopes to use that technology to develop therapies that edit genes "in vivo," meaning inside a patient rather than in a lab.

The deal between Moderna and Life Edit Therapeutics, announced Wednesday, will pair the former's mRNA platform with the latter's "suite of proprietary gene editing technologies," which includes DNA base editors and RGNs, or RNA-guided nucleases. While Moderna didn't disclose therapeutic targets, it did note how gene editing technology "has the potential to treat or cure rare genetic and other diseases." Financial terms also weren't disclosed.

Under their agreement, the companies will collaborate on research and preclinical studies. Moderna will fund those studies, and can take control of a program after a therapeutic target is selected, at which point it would be responsible for further development, manufacturing and commercialization.

J&J Loses Challenge to $302 Million Judgment Over Pelvic Mesh Marketing

Reuters reported:

The U.S. Supreme Court on Tuesday let stand a $302 million judgment against Johnson & Johnson (JNJ.N) in a lawsuit brought by the state of California accusing the company of concealing the risks of its pelvic mesh products.

California sued New Jersey-based J&J in 2016 in San Diego Superior Court. The case stemmed from a multistate investigation into J&J subsidiary Ethicon Inc.'s marketing of pelvic mesh devices, which are surgical implants that were used to treat incontinence and other conditions.

J&J and other mesh makers were already facing numerous private lawsuits by women who said they suffered pain, urinary problems, bleeding and other serious injuries from the devices. The lawsuits have resulted in more than $8 billion in settlements.

A Bitter Battle Over the 'Orphan Drug' Program Leaves Patients' Pocketbooks at Risk

Kaiser Health News reported:

A prescription drug that helps Lore Wilkinson walk and talk despite a rare muscle disease cost her so little for more than a decade that she didn't even use her insurance to pay for it. But now, her Medicare insurance is shelling out about $40,000 for a one-month supply of the drug, and she fears she'll be slammed with a $9,000 copayment.

Wilkinson, like millions of other people with rare diseases nationwide, is caught up in an ongoing legal and political debate about how the U.S. supports pharmaceutical companies and their research. The FDA made its latest move in the tug of war in late January by saying it would largely ignore a U.S. court ruling involving Firdapse, the drug Wilkinson needs.

Often, drugs granted exclusivity are among the highest priced in the U.S. market. For example, Zolgensma, a one-time treatment for spinal muscular atrophy, carries a $2.25 million price tag. Mary Carmichael, a spokesperson for its manufacturer, Novartis, said Zolgensma has treated more than 3,000 patients globally and nearly all U.S. patients taking the drug as approved by the FDA are covered by commercial or government insurance.

Influenza Vaccine Effectiveness Under 50% This Season: CDC Data

The Epoch Times reported:

Influenza vaccine effectiveness was under 50% this season, according to preliminary data from the U.S. Centers for Disease Control and Prevention (CDC), though a smaller study arrived at higher estimates.

Data from the CDC's New Vaccine Surveillance Network showed the vaccines were 49% effective against hospitalization or emergency department visits.

Preliminary results from a different CDC-run network, the Investigating Respiratory Viruses in the Acutely Ill (IVY) network, showed the vaccines were 43% effective against influenza A-associated hospitalizations among adults, including just 35% among adults aged 65 and older.

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